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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,746	12/22/2000	Stephen D. Ainsworth	ACS 54804 (23571)	6882

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EXAMINER

BAXTER, JESSICA R

ART UNIT PAPER NUMBER

3731

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary

Application No. 09/746,746		Applicant(s) AINSWORTH ET AL.	
Examiner Jessica R Baxter		Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2002 and 19 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-29 and 31-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-29 and 31-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2, 8, 9, 10, 11 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,190,403 to Fischell et al.

Regarding claims 1 and 2, Fischell discloses a stent comprising a plurality of cylindrical rings, having a first delivery diameter and a second implanted diameter, each cylindrical ring having a proximal end and a distal end defining a cylindrical wall extending circumferentially between the proximal end and the distal end of the cylindrical ring, at least one flexible link attaching each cylindrical ring to an adjacent cylindrical ring, the link including a bounded aperture with two aperture defining portions disposed generally transverse to the stent longitudinal axis (see Attached Figure 7).

Regarding claims 8 -10, Fischell discloses that the device further comprises an undulating link comprising at least one bend that is substantially straight and perpendicular to the longitudinal axis and is within the wall of the cylindrical ring (see Attached Figure 7).

Regarding claim 11, Fischell discloses that each cylindrical ring comprises peaks and valleys in phase with peaks and valleys of an adjacent cylindrical ring (see attached FIG 7).

Art Unit: 3731

Regarding claim 14, Fischell discloses that the stent is made of stainless steel (Column 3 lines 15-17).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3, 4, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. '403. Fischell discloses the invention as claimed except for the shape of the bounded aperture. It would have been an obvious matter of design choice to change the shape of the bounded aperture of Fischell, since it has been held to be within the general skill of a worker in the art to select a known shape on the basis of its suitability for the intended use as a matter of obvious design choice.

5. Claims 1, 12, 13 and 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over PG-PUB 2002/0151959 to Von Oepen in view of U.S. Patent No. 6,013,091 to Ley et al. Von Oepen discloses the claimed invention except for the bounded aperture disposed in the link. The bulged sections in the linked portions can be pulled from one another to create a larger opening in the wall of the stent (FIG. 1 and Paragraph 0005). Ley also discloses a bone shaped aperture that can be pulled to form a larger opening in the wall of the stent (FIGS. 3 and 4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the bulged section of Von Oepen with the dog bone-shape of Ley since they are equivalent structures used to expand the openings in the wall of the stent.

Art Unit: 3731

Regarding claims 18, 21-23, Ley discloses that the link comprises a radiused portion, an undulating link portion, a second undulating link portion, and a plurality of straight portions (see attached FIG. 3).

Regarding claim 25, Von Oepen discloses the stent is formed from a tube (Paragraph 0009).

6. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. '403 in view of U.S. Patent No. 5,925,061 to Ogi. et al. Fischell discloses the claimed invention except for the use of a shape memory alloy or a pseudo-elastic metal. Ogi teaches that pseudo-elastic metals and shape memory alloys are well known materials to make stents (column 6 lines 14-19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the stent of Fischell with the materials of Ogi since they are well known biocompatible materials used in the art.

7. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over PG-PUB 2002/0151959 to Von Oepen in view of U.S. Patent No. 6,013,091 to Ley et al., as applied to claims 17-25, further in view of EP 0806190 to Rolando et al. Von Oepen, as modified, discloses the claimed invention except for the varying cross sections of the plurality of struts that form the cylindrical rings. Rolando discloses varying the cross sections in order to achieve optimal characteristics of plastic deformability and resistance to stress, which may close the stent (see Column 11 line 31- Column 12 line 20). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cross sections of the plurality of struts of the modified invention of Von Oepen in order to optimize the characteristics of plastic deformability and resistance to stress.

8. Claims 27, 28, 29, 31, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/32543 to Penn et al. in view of Ogi et al. '061 further in view of

Art Unit: 3731

Ley et al. '091. Penn discloses a stent comprising a plurality of cylindrical rings (see FIG. 1) interconnected to form a stent, at least one flexible link (see FIG. 8 sidewalls 734 and 740) attaching each cylindrical ring to an adjacent cylindrical ring, and an undulating link (see FIG. 8 strut 770) within the wall of the ring (see Page 15 line 29- Page 16 line 7). Penn, as modified, discloses a stent comprising a plurality of cylindrical rings having a plurality of U-shaped portions (see FIG. 9 wall 860), Y-shaped portions and (see FIG. 9 wall 860 and portion 836) W-shaped portions (see FIG. 9 wall 850). Penn does not disclose a bounded aperture disposed in the link between the cylindrical rings. Ogi teaches that an aperture provides more compressibility in the direction aligned with the longitudinal axis of the stent and increases the bendability in radial directions (see Column 7 lines 52-67). Ley teaches that the tapered and radiused portions provide limited recoil of the stent and add resistance to compression of the stent (Column 1 lines 26-35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the stent of Penn with the aperture of Ogi in order to provide more compressibility in the direction aligned with the stent and to provide the stent of Penn with the radiused and tapered portions of Ley in order to add resistance to the compressibility and to provide limited recoil.

9. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/32543 to Penn et al. in view of Ogi et al. '061 and Ley et al. '091 as applied to claims 27, 28, 29, 31, 34, and 35, and further in view of EP 0806190 to Rolando et al. Penn, as modified, discloses the claimed invention except for the varying cross sections of the plurality of struts that form the cylindrical rings. Rolando discloses varying the cross sections in order to achieve optimal characteristics of plastic deformability and resistance to stress, which may close the stent (see Column 11 line 31- Column 12 line 20). Therefore, it

Art Unit: 3731

would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cross sections of the plurality of struts of the modified invention of Penn in order to optimize the characteristics of plastic deformability and resistance to stress.

Response to Arguments

10. Applicant's arguments with respect to claims 1-6, 8-19, 21-29 and 31-35 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731


jrb

February 9, 2003


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
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